

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	: Paul DiCarlo et al.	Art Unit	: 3736
Serial No.	: 10/728,248	Examiner	: Rene T. Towa
Filed	: December 4, 2003	Conf. No.	: 7802
Title	: MEDICAL INSTRUMENT		

**Mail Stop Appeal Brief - Patents**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

CORRECTED BRIEF ON APPEAL

**(1) Real Party in Interest**

The real party in interest is Boston Scientific SciMed, Inc.

**(2) Related Appeals and Interferences**

There are no related appeals or interferences.

**(3) Status of Claims**

Claims 1 and 4-33 are pending, stand rejected, and are under appeal.

Claims 2 and 3 are canceled.

**(4) Status of Amendments**

All amendments have been entered.

**(5) Summary of Claimed Subject Matter**

The invention relates to medical instruments, such as biopsy needle instruments. Claims 1, 15, and 22 are in independent form.

Claim 1 reads as follows:

1. A medical instrument, comprising:
  - a housing having a proximal end and a distal end;
  - a stylet having a portion in the housing, the stylet being axially movable between a first extended position and a first retracted position, the stylet being configured such that axial movement of the stylet from the first retracted position to the first extended position causes rotation of the stylet;

a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

FIG. 1A

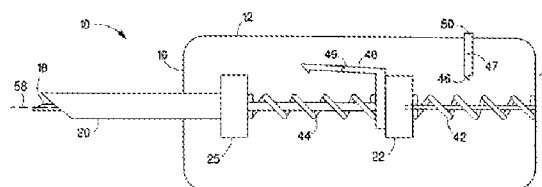
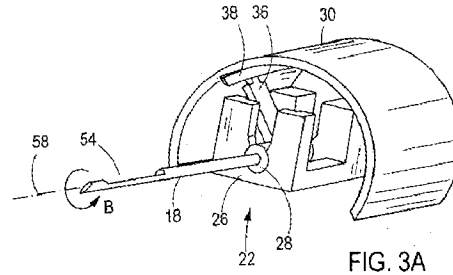
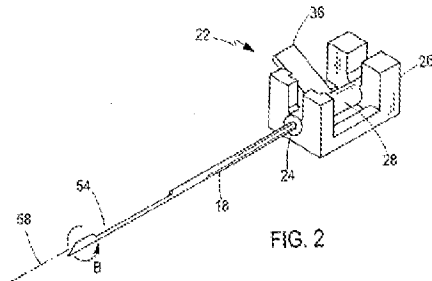


FIG. 1B

<sup>7</sup> See, e.g., *id.*, p. 3, line 31 – p. 4, line 1.

projection or an arm 36 extending radially outward from the inner part and engaging with a track 38.<sup>8</sup>



As shown in Figure 3A, track 38 can be an elongated channel defined in a curved, semi-cylindrical member 30 connected to housing 12.<sup>9</sup> In the illustrated embodiment, the track 38 extends helically in a direction parallel to axis 58 so that as spring 42 propels stylet block 22 distally during use, projection 36 travels along the track (e.g., distally and spirally) and rotates inner part 28 and stylet 18 (arrow B).<sup>10</sup> The rotational motion of stylet 18 can enhance its cutting action, thereby enhancing the performance of instrument 10.<sup>11</sup>

Claim 15 reads as follows:

15. A method of using a medical instrument, the method comprising:  
moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet;  
simultaneously causing rotation of the stylet along an axis of the stylet by contact between the second part of the stylet block and a housing of the medical instrument; and  
moving a cannula over the stylet.

During use, stylet 18 and cannula 20 (as described above) are loaded or cocked to their retracted positions, ready to be triggered.<sup>12</sup> Moving stylet 18 to its retracted position compresses spring 42.<sup>13</sup> When stylet 18 and cannula 20 are triggered, the spring 42 propels stylet block 22 and stylet 18 distally to their extended positions, e.g., to collect a tissue specimen.<sup>14</sup>

Claim 22 reads as follows:

<sup>8</sup> See, e.g., id., p. 4, lines 1-3.

<sup>9</sup> See, e.g., id., p. 4, lines 3-4.

<sup>10</sup> See, e.g., id., p. 4, lines 4-8; and p. 5, lines 22-24.

<sup>11</sup> See, e.g., id., p. 3, lines 27-28.

<sup>12</sup> See, e.g., id., p. 3, lines 22-23.

<sup>13</sup> See, e.g., id., p. 5, lines 10-17.

<sup>14</sup> See, e.g., id., p. 3, lines 23-25; and p. 5, lines 20-22.

22. A medical instrument, comprising:  
a housing having a proximal end and a distal end;  
a stylet having a portion in the housing, the stylet being movable between a first extended position and a first retracted position, the stylet being configured to rotate when moved from the first retracted position to the first extended position;  
a cannula coaxially receiving the stylet and having a portion in the housing, the cannula being movable between a second extended position and a second retracted position; and  
a stylet block, the stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:  
a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and  
a second part attached to the proximal end of the stylet, the second part being rotatably engaged and in contact with the first part and being able to rotate relative to an axis of the stylet.

Figures 1A and 1B of the appellants' application (reproduced above), illustrate a medical instrument 10 (as shown, a needle biopsy device) which includes a housing 12, a stylet 18, and a cannula 20 coaxially receiving the stylet.<sup>15</sup> Both stylet 18 and cannula 20 can be moved between retracted positions as shown in Figure 1A and extended positions as shown in Figure 1B.<sup>16</sup> During use, stylet 18 and cannula 20 are loaded or cocked to their retracted positions, ready to be triggered.<sup>17</sup> Moving stylet 18 to its retracted position compresses spring 42.<sup>18</sup> When stylet 18 and cannula 20 are triggered, the spring 42 propels stylet block 22 and stylet 18 distally to their extended positions, e.g., to collect a tissue specimen.<sup>19</sup>

Figures 2 and 3A of the appellants' application (reproduced above) illustrate stylet block 22 in more detail. Stylet block 22 includes a first, outer part 26 and a second, inner part 28.<sup>20</sup> The inner part 28 is attached to the proximal end 24 of stylet 18 and can rotate within outer part 26, about the longitudinal axis 58 of the stylet.<sup>21</sup> The inner part 28 includes a projection or an arm 36 extending radially outward from the inner part and engaging with a track 38.<sup>22</sup>

As shown in Figure 3A, track 38 can be an elongated channel defined in a curved, semi-cylindrical member 30 connected to housing 12.<sup>23</sup> In the illustrated embodiment, the track 38

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<sup>15</sup> See, e.g., Application, p. 3, lines 15-17.

<sup>16</sup> See, e.g., id., p. 3, lines 20-22.

<sup>17</sup> See, e.g., id., p. 3, lines 22-23.

<sup>18</sup> See, e.g., id., p. 5, lines 10-17.

<sup>19</sup> See, e.g., id., p. 3, lines 23-25; and p. 5, lines 20-22.

<sup>20</sup> See, e.g., id., p. 3, lines 30-31.

<sup>21</sup> See, e.g., id., p. 3, line 31 – p. 4, line 1.

<sup>22</sup> See, e.g., id., p. 4, lines 1-3.

<sup>23</sup> See, e.g., id., p. 4, lines 3-4.

extends helically in a direction parallel to axis 58 so that as spring 42 propels stylet block 22 distally during use, projection 36 travels along the track (e.g., distally and spirally) and rotates inner part 28 and stylet 18 (arrow B).<sup>24</sup> The rotational motion of stylet 18 can enhance its cutting action, thereby enhancing the performance of instrument 10.<sup>25</sup>

#### **(6) Grounds of Rejection to be Reviewed on Appeal**

Claims 1, 4-11, 15, and 20-30 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,045 ("Clement") in view of U.S. Patent No. 5,197,484 ("Kornberg"), and further in view of U.S. Patent No. 5,467,684 ("Sher").

Claims 12, 14, 31, and 33 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher, and further in view of U.S. Patent No. 5,921,943 ("Kass").

Claims 13 and 32 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher, further in view of U.S. Patent No. 5,394,887 ("Haaga").

Claim 16 was rejected under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher, further in view of U.S. Patent No. 6,331,166 ("Burbank").

Claims 17-19 were rejected under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher, further in view of U.S. Patent No. 5,649,547 ("Ritchart").

#### **(7) Argument**

Rejection of claims 1, 4-11, 15, and 20-30 under 35 U.S.C. 103(a) as being unpatentable over Clement in view of U.S. Patent No. 5,197,484 Kornberg, and further in view of Sher.

Claim 1 recites

**a stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:**

**a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and**

**a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.**

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<sup>24</sup> See, e.g., id., p. 4, lines 4-8; and p. 5, lines 22-24.

<sup>25</sup> See, e.g., id., p. 3, lines 27-28.

Claim 15 recites

**moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet;**

Claim 22 recites

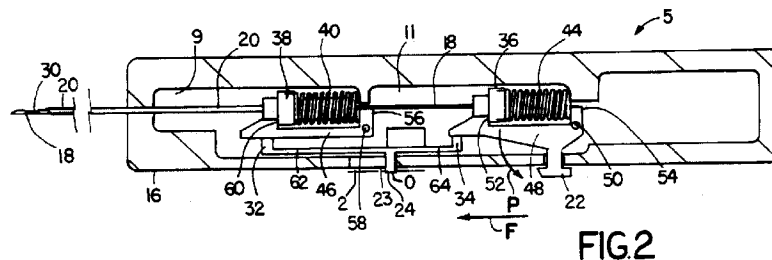
**a stylet block, the stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:**

**a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and**

**a second part attached to the proximal end of the stylet, the second part being rotatably engaged and in contact with the first part and being able to rotate relative to an axis of the stylet.**

The cited references, alone or in combination, do not describe or make obvious medical instruments or methods of using medical instruments with the stylet blocks as claimed by the appellants.

Clement does not describe a stylet block as claimed by the appellants. Rather Clement describes a biopsy device with a stylet retaining collar 36 as shown in Clement's Fig. 2 (reproduced below).



The appellants have been unable to find any indication that Clement's retaining collar 36 is rotatably engaged with any other parts. The final office action acknowledges that

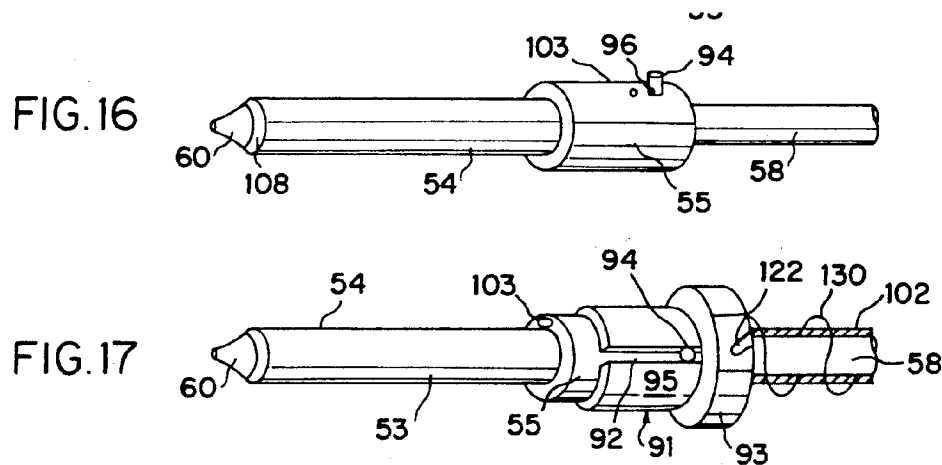
**Clement et al. disclose a system, as described above, that fails to teach a stylet configured to rotate when moved from the first retracted position to the first extended position.<sup>26</sup>**

Thus, Clement does not disclose a stylet block with, for example, "a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet" (claim 1).

<sup>26</sup> Office action dated May 21, 2009, page 4.

Neither Kornberg not Sher remedy this deficiency of Clement.

Kornberg discloses a device with a stylet 58 coaxially received by a cannula 54.<sup>27</sup> As shown in Kornberg's FIG. 16, (reproduced below), the cannula includes a larger diameter section 55 that is fixedly secured to driving pin 94. Driving member 91 engages driving pin 94 as illustrated in Kornberg's FIG. 17 (reproduced below) and, thus, rotation of driving member 91 causes rotation of driving pin 94 and attached cannula 54. Because driving pin 94 also extends into within spiral cam channel 158, the rotation of driving pin 94 causes forward movement of the driving pin 94 and attached cannula 54.

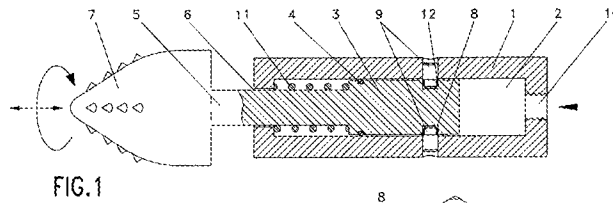


Thus, cannula section 55, driving pin 94, and driving member 91 rotate together but they are not rotatably engaged to each other.

Rather than a stylet block with a first part and a second part rotatably engaged with the first part and being able to rotate relative to an axis of the stylet, Sher discloses a piston 3 with a wave-shaped groove 8 defined in its outer surface which engages guide members 9 extending inward from a housing (see Sher's FIG. 1 reproduced below) or, in an alternate embodiment, a piston 3 with guide members 9 extending outward from the piston to a wave-shaped groove defined in the housing.<sup>28</sup>

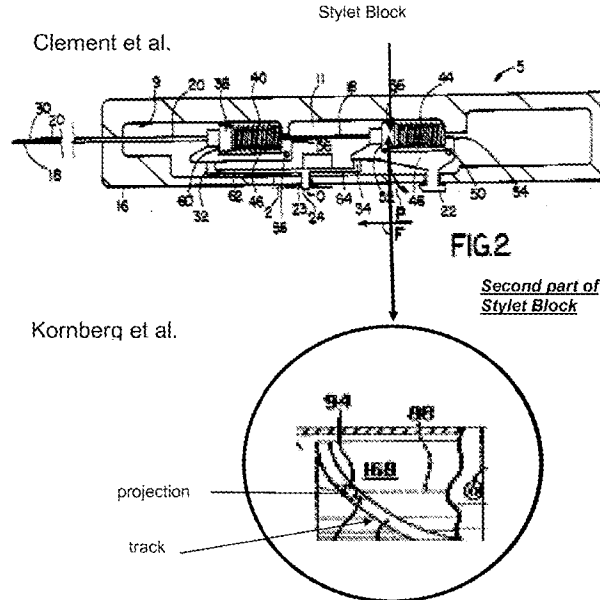
<sup>27</sup> See Kornberg, FIGS. 11-13 and col. 8, line 63 – col. 10, line 59.

<sup>28</sup> See, e.g., Sher, col. 3, lines 29-64, col. 5, lines 56-60, and abstract.



Thus, neither Clement, Kornberg, not Sher describe a stylet block with a first part moveable between an extended position and a retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

In the final office action, the examiner provided the annotated figures reproduced below



and asserted

**that Kornberg et al. disclose a biopsy medical system including a second part "having a projection 94 in contact with a track 158 associated with a housing 70; wherein the track 158 is configured to provide unidirectional rotation to the cannula 54; wherein the track is configured to provide multidirectional rotation to the cannula 54 [citations omitted]." As such, the Examiner submits that Clement et al. fully teach a stylet block and Kornberg et al. fully teach a second part comprising a projection and track.<sup>29</sup>**

In the advisory action, the examiner clarified that, rather than asserting that the projection 94 and track 158 described by Kornberg are equivalent to the second part of the stylet block as recited by the applicant's claims, he meant that

<sup>29</sup> Office action dated May 21, 2009, page 10.

**the stylet block (i.e. collar 36) of Clement et al. include a first part (i.e. the part of the stylet block that carries the stylet 18), which part is fully located within a cavity 11 of the housing 16 (see col. 3, lines 22- 27); wherein the stylet block 36 with the first part are moveable between an extended position and a retracted position (see figs. 3a & 4a; col. 3, lines 63-67). Similarly, Kornberg teaches a cannula block comprising a second part (i.e. the projection 94 and larger diameter 55), the second part 94 is attached to a proximal end of the cannula 54 via larger diameter section 55 (see figs. 14-17).<sup>30</sup>**

However, as discussed above, Kornberg's driving pin 94 that the examiner characterizes as the second part is not rotatably attached another part of the block.

The examiner asserts that

**a combination of Clement et al. and Kornberg, as described in the Office action, entails adding part of the rotary motion mechanism of Kornberg et al. into the biopsy needle instrument of Clement et al. Such rotary motion mechanism may involve the use of a larger diameter section 55 of Kornberg et al. to carry the stylet 18 onto the retainer block 36 of Clement et al., which still need to be able to move forward and backward, along with a projection 94 and enlarged section 55 of Kornberg that is able to rotate relative to an axis of the stylet 18 of Clement et al..<sup>31</sup>**

The appellants traverse. If the device described by Clement were modified to use the projection / track mechanism described by Kornberg, Clement's device would no longer require its original stylet block and, thus, the modified device would not include a stylet block comprising: a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

In addition, the proposed motivation for combining the references lacks the rational underpinning necessary to sustain an obviousness rejection.<sup>32</sup> The office action makes the conclusory statement that "it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. with a simultaneously rotating and forwardly driven cannula mechanism as taught by Kornberg et al. in order to automatically rotate the cannula as it penetrates tissue so as to facilitate tissue

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<sup>30</sup> Advisory action dated August 27, 2009, page 3.

<sup>31</sup> Id., pages 3 and 4.

<sup>32</sup> See *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 at 1740 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness" – emphasis added).

penetration.”<sup>33</sup> However, the examiner has not provided any reason that a person of ordinary skill in the art who was aware of Clement and Kornberg and who desired a biopsy device with an automatically rotating cannula would modify the device described by Clement rather than just using the device described by Kornberg. Further, the appellants submit that, in the absence of a detailed analysis of Appellants’ disclosure, a person of ordinary skill in the art with Kornberg’s biopsy device in hand would have no reason to investigate the field of piston-driven cutting devices and drills to uncover Sher. Thus, only impermissible hindsight reconstruction would provide a basis for the proposed combination of references. However, one cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.<sup>34</sup> For at least these reasons, the examiner’s articulated reason for modifying Clement and proposed combination of references lacks the rational underpinning necessary to support the legal conclusion of obviousness.<sup>35</sup>

The final office action asserts that

**it would have been obvious to one of ordinary skill in the art at the time Applicant's invention was made to provide the system of Clement et al. as modified by Kornberg and Sher above with a driving mechanism such that linear displacement of the stylet causes rotational motion of the stylet as claimed in order to automatically simultaneously rotate and advance the stylet through the tissue.**<sup>36</sup>

Whether or not this assertion is correct, the appellants have claimed, for example, a stylet block comprising: “a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet” (claim 1) rather than “a driving mechanism such that linear displacement of the stylet causes rotational motion of the stylet as claimed in order to automatically simultaneously rotate and advance the stylet through the tissue.”<sup>37</sup> Thus, the cited

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<sup>33</sup> Office action dated May 21, 2009, pages 4-5.

<sup>34</sup> *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600. See also *KSR International Co. v. Teleflex Inc. et al.*, 127 S.Ct. 1727 at 1742 (“A fact finder should be aware, of course, of the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post* reasoning.”)

<sup>35</sup> See *KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 127 S.Ct. 1727 at 1740 (2007) citing *In re Kahn*, 441 F.3d 977, 988 (C.A.Fed. 2006) (“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness” – emphasis added).

<sup>36</sup> Office action dated May 21, 2009, pages 4-5.

<sup>37</sup> *Id.*, page 5.

references have not been shown to describe all the features claimed of the devices and methods claimed by the appellants and do not support a prima facie case of obviousness.

For at least these reasons, none of the cited references has been shown to disclose or make obvious a stylet block with a first part moveable between an extended position and a retracted position; and a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet. Accordingly, Clement, Kornberg, and Sher, in combination or in further view of Kass; Haaga; Burbank; or Ritchart do not provide the basis for a prima facie case of obviousness of the pending claims.

*Dependent claims 5 and 24*

Dependent claims 5 and 24 further distinguish the cited art.

Claims 5 specifies that

**the second part comprises:  
a projection in contact with a track associated with the housing, the projection and track capable of cooperating to axially rotate the second part and the attached stylet when the stylet is moved between the first extended position and the first retracted position.**

Dependent claim 24 specifies that the second part of the stylet block includes

**a projection in contact with a track associated with the housing, the projection and track capable of cooperating to axially rotate the second part and the attached stylet when the stylet block is moved between the third extended position and the third retracted position.**

These claims clarify that the housing with associated track is in contact with the second part of the stylet block rather than being part of the stylet block.

For at least these reasons, neither Clement nor Kornberg nor Sher, alone or in combination, discloses or makes obvious the medical instruments covered by claims 1, 4-11,15, and 20-30. Even if the references were combined, the result would not be the medical devices covered by claims 1, 4-11,15, and 20-30.

Rejection of claims 12, 14, 31, and 33 under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher further in view of Kass

Claims 12 and 14 depend from claim 1 and claims 31 and 33 depend from claim 22. The examiner asserts that Kass discloses the features of the stylet notch recited by claims 12, 14, 31,

and 33.<sup>38</sup> However, neither the stylet nor the cannula rotate in the biopsy system described by Kass. Thus, Kass does not cure the deficiencies of the proposed combination of Clement, Kornberg, and Sher as discussed above with respect to independent claims 1 and 22. None of Clement, Kornberg, Sher, and Kass, alone or in combination, discloses or makes obvious the medical instruments covered by claims 12, 14, 31, and 33. Even if the references were combined (which the Appellants do not concede is appropriate), the result would not be the medical devices covered by claims 12, 14, 31, and 33. Accordingly, the appellants request that the board overrule the rejection of claims 12, 14, 31, and 33 as being unpatentable over Clement in view of Kornberg and Sher further in view of Kass.

Rejection of claims 13 and 32 under 35 U.S.C. 103(a) as being unpatentable over  
Clement in view of Kornberg further in view of Haaga

Claim 13 depends from claim 1 and claim 32 depends from claim 22. The examiner asserts that Haaga discloses the features of the stylet notch recited by claims 13 and 32.<sup>39</sup> However, neither the stylet nor the cannula rotate in the biopsy system described by Haaga. Thus, Haaga does not cure the deficiencies of the proposed combination of Clement and Kornberg as discussed above with respect to independent claims 1 and 22. None of Clement, Kornberg, and Haaga, alone or in combination, discloses or makes obvious the medical instruments covered by claims 12, 14, 31, and 33. Even if the references were combined (which the Appellants do not concede is appropriate), the result would not be the medical devices covered by claims 13 and 32. Accordingly, Appellants request that the board overrule the rejection of claims 13 and 32 as being unpatentable over Clement in view of Kornberg further in view of Haaga.

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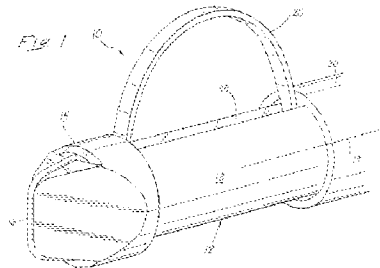
<sup>38</sup> See Office Action mailed February 25, 2008, p. 5.

<sup>39</sup> See Office Action mailed February 25, 2008, p. 6.

Rejection of claims 16 under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher further in view of Burbank

Claim 16 depends from claim 15. The examiner asserts that Burbank discloses oscillating the stylet 18 along the axis.<sup>40</sup> However, Burbank does not disclose or make obvious “[a] stylet block having an axially moveable first part and a second part attached to the stylet, the second part being rotatably engaged with the first part” nor “simultaneously causing rotation of the stylet along an axis of the stylet by contact between the second part of the stylet block and a housing of the medical instrument” as recited by claim 15.

Rather Burbank describes a cutting element 20 (illustrated in Burbank's FIG. 1 reproduced below) that was previously characterized by the Examiner as a stylet block.<sup>41</sup> But, cutting element 20 is attached to a rod 32 rather than contacting housing 28.<sup>42</sup> Rotation of shaft 18 (characterized by the Examiner as a stylet) causes rotation of cutting element 20 rather than engagement of cutting element 20 with another element causing rotation of shaft 18.<sup>43</sup> Therefore, engagement between cutting element 20 and housing 28 does not cause rotation of a stylet.



Thus, Burbank does not cure the deficiencies of the proposed combination of Clement, Kornberg, and Sher as discussed above with respect to independent claim 15. None of Clement, Kornberg, Sher, and Burbank, alone or in combination, discloses or makes obvious the medical instruments covered by claim 16. Even if the references were combined (which the Appellants do not concede is appropriate), the result would not be the medical devices covered by claim 16.

<sup>40</sup> See Office Action mailed February 25, 2008, p. 7.

<sup>41</sup> Office Action mailed June 1, 2007, p. 4.

<sup>42</sup> See Burbank, col. 5, lines 35-62.

<sup>43</sup> See id., col. 5, lines 35-42.

Accordingly, Appellants request that the board overrule the rejection of claim 16 as being unpatentable over Clement in view of Kornberg and Sher, further in view of Burbank.

Rejection of claims 17-19 under 35 U.S.C. 103(a) as being unpatentable over Clement in view of Kornberg and Sher, further in view of Ritchart

Claims 17-19 depend from claim 15. The examiner asserts that Ritchart discloses the features recited by claims 17-19.<sup>44</sup> However, neither the stylet nor the cannula rotate in the biopsy system described by Ritchart. Thus, Ritchart does not cure the deficiencies of the proposed combination of Clement, Kornberg, and Sher as discussed above with respect to independent claim 15. None of Clement, Kornberg, Sher, and Ritchart, alone or in combination, discloses or makes obvious the medical instruments covered by claims 17-19. Even if the references were combined, the result would not be the medical devices covered by claims 17-19. Accordingly, Appellants request that the board overrule the rejection of claims 17-19 as being unpatentable over Clement in view of Kornberg and Sher, further in view of Ritchart.

Conclusion

In view of the foregoing discussion, the appellants request that the board overrule the rejection of claims 1 and 4-33 as being unpatentable over the cited references.

Appellant previously paid the appropriate fee in connection with filing an appeal brief and therefore believes that no fee is due. Please apply any charges or credits to Deposit Account No. 06 1050, referencing attorney docket no 01194-0824001.

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<sup>44</sup> See Office Action mailed February 25, 2008, p. 7.

Applicant : Paul DiCarlo et al.  
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Filed : December 4, 2003  
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Attorney's Docket No.: 01194-0824001 / 03-088

Respectfully submitted,

Date: February 10, 2010

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### **Appendix of Claims**

1. (Previously Presented) A medical instrument, comprising:

a housing having a proximal end and a distal end;

a stylet having a portion in the housing, the stylet being axially movable between a first extended position and a first retracted position, the stylet being configured such that axial movement of the stylet from the first retracted position to the first extended position causes rotation of the stylet;

a cannula coaxially receiving the stylet and having a portion in the housing, the cannula being movable between a second extended position and a second retracted position; and

a stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:

a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and

a second part attached to the proximal end of the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet.

2-3. (Canceled)

4. (Previously Presented) The instrument of claim 3, wherein the housing comprises a semi-cylindrical portion defining a track configured to engage with the second part.

5. (Previously Presented) The instrument of claim 3, wherein the second part comprises:

a projection in contact with a track associated with the housing, the projection and track capable of cooperating to axially rotate the second part and the attached stylet when the stylet is moved between the first extended position and the first retracted position.

6. (Previously Presented) The instrument of claim 5, wherein the track is molded into the interior side of the housing.

7. (Previously Presented) The instrument of claim 5, wherein the track is configured to provide unidirectional rotation to the stylet.

8. (Previously Presented) The instrument of claim 5, wherein the track is configured to provide multidirectional rotation to the stylet.

9. (Previously Presented) The instrument of claim 1, further comprising:  
a stylet spring capable of moving the stylet from the first retracted position to the first extended position; and

a cannula spring capable of moving the cannula from the second retracted position to the second extended position.

10. (Previously Presented) The instrument of claim 1, further comprising:  
a first pivoting latch capable of retaining the stylet in a predetermined position when the stylet is in the first retracted position; and  
a second pivoting latch capable of retaining the cannula in a predetermined position when the cannula is in the second retracted position.

11. (Previously Presented) The instrument of claim 1 wherein the stylet comprises a notch with a sharpened leading edge.

12. (Previously Presented) The instrument of claim 1, wherein the stylet comprises a notch having two openings.

13. (Previously Presented) The instrument of claim 1, wherein the stylet comprises a notch with a ramped surface.

14. (Previously Presented) The instrument of claim 13, wherein the stylet further comprises an opening opposing the notch.

15. (Previously Presented) A method of using a medical instrument, the method comprising:

moving a stylet and a stylet block from a first position to a second position, the stylet block having an axially moveable first part and a second part attached to the stylet, the second part being rotatably engaged with the first part and being able to rotate relative to an axis of the stylet;

simultaneously causing rotation of the stylet along an axis of the stylet by contact between the second part of the stylet block and a housing of the medical instrument; and

moving a cannula over the stylet.

16. (Previously Presented) The method of claim 15, further comprising oscillating the stylet along the axis.

17. (Previously Presented) The method of claim 15, further comprising collecting a sample in a notch of the stylet.

18. (Previously Presented) The method of claim 17, further comprising removing the sample from the notch by inserting an object through an opening located in the notch.

19. (Previously Presented) The method of claim 17, further comprising removing the sample over an inclined portion of the notch.

20. (Previously Presented) The method of claim 15, comprising rotating the stylet in one direction.

21. (Previously Presented) The method of claim 15, comprising rotating in multiple directions.

22. (Previously Presented) A medical instrument, comprising:  
a housing having a proximal end and a distal end;  
a stylet having a portion in the housing, the stylet being movable between a first extended position and a first retracted position, the stylet being configured to rotate when moved from the first retracted position to the first extended position;  
a cannula coaxially receiving the stylet and having a portion in the housing, the cannula being movable between a second extended position and a second retracted position; and  
a stylet block, the stylet block attached to a proximal end of the stylet and mounted inside the housing, the stylet block comprising:  
a first part inside the housing, the first part being moveable between a third extended position and a third retracted position; and  
a second part attached to the proximal end of the stylet, the second part being rotatably engaged and in contact with the first part and being able to rotate relative to an axis of the stylet.

23. (Previously Presented) The instrument of claim 22, wherein the housing comprises a semi-cylindrical portion defining a track configured to engage with the second part.

24. (Previously Presented) The instrument of claim 22, wherein the second part comprises:

a projection in contact with a track associated with the housing, the projection and track capable of cooperating to axially rotate the second part and the attached stylet when the stylet block is moved between the third extended position and the third retracted position.

25. (Previously Presented) The instrument of claim 24, wherein the track is molded into the interior side of the housing.

26. (Previously Presented) The instrument of claim 24, wherein the track is configured to provide unidirectional rotation to the stylet.

27. (Previously Presented) The instrument of claim 24, wherein the track is configured to provide multidirectional rotation to the stylet.

28. (Previously Presented) The instrument of claim 22, further comprising:  
a stylet spring capable of moving the stylet from the first retracted position to the first extended position; and

a cannula spring capable of moving the cannula from the second retracted position to the second extended position.

29. (Previously Presented) The instrument of claim 22, further comprising:  
a first pivoting latch capable of retaining the stylet in a predetermined position when the stylet is in the first retracted position; and  
a second pivoting latch capable of retaining the cannula in a predetermined position when the cannula is in the second retracted position.

30. (Previously Presented) The instrument of claim 22, wherein the stylet comprises a notch with a sharpened leading edge.

31. (Previously Presented) The instrument of claim 22, wherein the stylet comprises a notch having two openings.

32. (Previously Presented) The instrument of claim 22, wherein the stylet comprises a notch with a ramped surface.

33. (Previously Presented) The instrument of claim 32, wherein the stylet further comprises an opening opposing the notch.

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### **Evidence Appendix**

None.

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### **Related Proceedings Appendix**

None.